Healthcare Common Procedure Coding System (HCPCS)
LEVEL II CODE MODIFICATION REQUEST PROCESS
The 2017 HCPCS Update

The Healthcare Common Procedure Coding System (HCPCS) Level II contains alphanumeric codes used to identify items (and sometimes, services) that are not included in the HCPCS Level I (American Medical Association's CPT) code set.

As a preliminary step in the process for recommending a modification to the HCPCS Level II coding system, it may be helpful for you to contact 3rd party payers for Medicare, Medicaid and private insurers to determine if, in their determination, existing HCPCS codes identify the item.

You may submit a recommendation to establish, revise or discontinue a code, using the attached, standard format. Please prepare a cover letter outlining your code request and a brief summary of why the code modification is needed. In addition to providing the information according to the format, please include descriptive material, which you think would be helpful in furthering our understanding of the medical benefits of the item for which a coding modification is being recommended. Submit one signed original request with supporting documentation plus 35 copies of your entire original recommendation information packet (36 applications in total). Receipt of the copies helps expedite distribution to HCPCS workgroup members. At this time, we are not able to accommodate electronic requests, and all originals requests and copies must be submitted on paper.

In order to ensure timely review of your materials, it is necessary to limit your recommendations to no more than 40 pages. Completed applications must include questions exactly as written in the application, and your answers. Applications exceeding 40 pages will not be accepted.

Applicants making a claim of “significant therapeutic distinction” to distinguish a product from its current coding in an existing code category (refer to item 7c on the application) may find a need to exceed the 40-page limit in order to submit relevant substantiating clinical information. In these cases only, the applicant may exceed the 40-page limit only for relevant substantiating clinical information. The clinical information must be included with the original application and all 35 copies.

Each side of a page; including brochures, booklets, and any other inclusions, counts as one page in calculating the 40 page limit. The completed, signed and dated format, including required FDA clearance (approval letter or explanation of exemption), and package insert and any other supporting documentation, such as, but not limited to product brochures and/or booklets are all included in the 40-page application limit; all pages of each
application should be bundled securely to ensure that it arrives intact. **Please note that FDA approval for drug coding applications may be submitted after the initial application but no later than March 31st**, (refer to detailed application instructions).

Please **do not use** bulky materials, such as 3-ring binders, to fasten recommendation materials, as this may result in difficulties distributing materials to reviewers.

To ensure that applications are not overlooked, separate applications should be submitted in different packages. We do not require or ask for samples. However, many applicants ask if they may send product samples, video tapes or compact discs as a supplement to their application. If it is practical and feasible for an applicant to submit a sample with their application, they may voluntarily do so, however, it becomes the property of CMS to keep or dispose of as the agency sees fit. If the applicant chooses to send samples, video tapes, or compact discs, please send no more than 3.

**CMS’ REVIEW PROCESS AND RECONSIDERATION PROCESS PUBLIC NOTICE AND OPPORTUNITIES FOR PUBLIC INPUT**

All timely and complete recommendations are distributed to all reviewers; placed on HCPCS Meeting Agendas; and reviewed at regularly scheduled meetings by a panel whose membership includes representatives all government and non-government insurance sectors; including of Medicaid, Medicare, the Private Insurance sector and The Department of Veteran’s Affairs.

All external recommendations, (e.g. requests not generated internally) will be placed on a Public Meeting Agenda together with the preliminary HCPCS coding decision. The HCPCS Public Meetings provide an open forum for interested parties to make oral presentations or to submit written comments in response to published preliminary coding decisions. A Federal Register notice will be published to announce dates, times and the location of the public meetings. We will also post on CMS’ official Level II HCPCS website at [www.cms.gov/medhcpcsgeninfo](http://www.cms.gov/medhcpcsgeninfo) the dates, times, agendas, preliminary coding recommendations, registration information and guidelines for participation in HCPCS Public Meetings. Although the Public Meetings are not decision-making meetings, they provide an opportunity for applicants and the general public to react to preliminary coding decisions and share additional information with decision makers, prior to final decisions, and as such, CMS’ Public Meeting process provides a reconsideration opportunity.

All applicants will be notified, in writing, of the final decision on their application by mid-November 2016. All modifications to the HCPCS codes set will be incorporated into the 2017 HCPCS Level II Annual update, which will be published on CMS’ official HCPCS Level II worldwide website at [www.cms.gov/medhcpcsgeninfo](http://www.cms.gov/medhcpcsgeninfo) by mid-November 2016. A summary of all external applications, including CMS’ final decisions and rationale will also be published on the same website.
APPLICATION DEADLINE

To be considered for inclusion in CMS’ year 2017 Annual HCPCS update, completed recommendation packets must be received no later than close of business (COB) Monday, January 4, 2016. The HCPCS coding review process is an ongoing, continuous process. Requests for the 2016-2017 coding cycle may be submitted at any time following the 2015 application deadline, and up to January 4, 2016. Early submissions are strongly encouraged.

Only complete and timely requests will be accepted. Applications for products/services that are not yet available on the U.S. market will be considered incomplete. **Recommendations submitted for the 2016-2017 coding cycle that are received or completed on or after COB January 4, 2016 will not be processed.** Applications exceeding the 40-page limit are not acceptable with the single exception as noted on page 1 of these instructions and in question 7c of this application.

For additional detailed information regarding the HCPCS coding process or the application process, you may: 1) review documents on website at [www.cms.gov/medhcpcsgeninfo](http://www.cms.gov/medhcpcsgeninfo); 2) submit an inquiry to HCPCS@cms.hhs.gov; or 3) contact CMS HCPCS staff; Cynthia Hake at (410) 786-3404, Judi Wallace 410-786-3197 or Kimberlee Combs Miller (410) 786-6707.

REQUIRED INFORMATION

**Alpha-Numeric Coding Recommendation Format for the 2017 Update**

**Instructions:**

1. Please **sign and date** each recommendation. Be certain to provide the name, complete mailing address, direct telephone number, fax number and e-mail address of the applicant. We use this information to contact applicants regarding upcoming meetings, questions regarding applications, and to make notifications of the status of applications. Please be sure that your system can receive emails from cms.hhs.gov.

2. When the applicant is not the manufacturer, **the manufacturer must also sign** the application and provide contact information as instructed at item 14b and 14c of the application. The manufacturer’s attestation and signature must be part of the original application and may not be an addendum page or separately submitted.

3. Foreign applicants (those residing outside the U.S.) must provide a U.S. primary contact with U.S. contact information.

4. Please provide documentation of the item's current classification by the Food and Drug Administration (FDA). **Include a copy of the cover page from the initial FDA application; a copy of the FDA's determination, notification/approval letter, and FDA approved package insert.** If the drug/biological/product/service has been subject to an assessment by any other agency or recognized medical body, provide a copy of the results of that assessment.
Documentation of FDA approval of a drug or biological may be submitted after the coding application but no later than March 31st, provided all other requested information is complete and submitted by the application deadline.

5. All requested information must be supplied before your recommendation for modifications to the HCPCS coding system can be considered. All application questions in CMS’ format must be transferred to your application exactly as they appear in CMS’ Coding Recommendation format. All questions must be answered fully. If a question does not appear to apply, provide a detailed explanation as to why it doesn't apply. “N/A” responses are considered a non-response, and will make the application incomplete. Incomplete submittals will not be accepted.

6. Repeat applications must include information within the application that is new and different from prior application that is intended to overcome a prior decision. In addition, please make it clear in your cover letter that this is a repeat application, and highlight any new/different information in the application.

7. Submit Coding Recommendations to:

   Cynthia Hake, Director, CMS’ National Level II HCPCS Coding Program
   Centers for Medicare and Medicaid Services
   C5-09-14
   7500 Security Blvd
   Baltimore, Maryland 21244-1850
Alpha-Numeric HCPCS Coding Recommendation Format

INFORMATION SUPPORTING CODING MODIFICATION RECOMMENDATION

1.) For the purpose of publication on our request list and public meeting agenda on the HCPCS website, please provide a brief summary of your request (not to exceed 300 words). In this summary, please specify your request to modify the HCPCS code set: (e.g. number of new codes requested, recommended language; revise a code (provide old language and recommended language), discontinue a code). Include the name of the product, description, function, and the reason why existing codes do not adequately describe your product. For drugs, include the indications for use, action, dosage and route of administration, and how supplied. Text that exceeds the 300-word limit may be truncated and not appear on our published summary, therefore, it is important to provide a concise summary within the 300-word limit. CMS may edit your summary prior to publication.

2. Identify the Item (product or drug/biological) for which a Level II HCPCS Code is being requested.

A) Trade or Brand Name:
B) General Product Name or Generic Drug Name (active ingredient):
C) FDA classification:

3. Please check one HCPCS category from the following list, which in your estimation most accurately describes the item identified in question #1:

__ A) Medical/Surgical Supplies
__ B) Dialysis Supplies and Equipment
__ C) Ostomy/Urological Supplies
__ D) Surgical Dressing
__ E) Prosthetic
__ F) Orthotic
__ G) Enteral/Parenteral Nutrition
__ H) Durable Medical Equipment
__ I) Blood/Blood Products
__ J) Drug/Biological
__ K) Radiopharmaceutical
__ L) Vision
__ M) Hearing
__ N) Other (please indicate/provide category)
4a.) Is the item durable, if so; explain how it can withstand repeated use?
Specify whether the entire item or only certain components of the item can withstand repeated use:
4b.) If the entire item can withstand repeated use, then please specify the length of the time that the item can withstand repeated use.
4c.) If only certain components of the device can withstand repeated use, then please identify the individual components and the length of the time that the individual components can withstand repeated use.
4d.) Please provide detailed information on the warranty of the device such as the parts included under the warranty, the length of the warranty and the parts excluded from the warranty. In addition, please specify if the device includes any disposable components and the expected life or the replacement frequency recommended for the disposable components.

5.) Describe the item fully in general terminology. What is it? What does it do? How is it used? Describe the patient population for whom the product is clinically indicated.
Descriptive booklets, brochures, package inserts, as well as copies of published peer-reviewed articles on the item may be included in the information packet submitted for review, but they do not replace the requirement to fully respond to this question and fully describe the item.
Responses for drugs and biologicals must include: A) indications for use, B) action, C) dosage and route of administration, D) package insert and, E) how supplied.

6.) Describe how the item/product is primarily and customarily used to serve a medical purpose.

**Significant Therapeutic Distinction**

7a.) Identify similar products and their manufacturers.
(If a drug - list other drugs by trade name marketed under the same active ingredient category/generic name.)

7b.) Identify significant differences between this item and other products listed above.
(Include differences in item cost; material; product design; how it is used; different mechanism of operation, differences in function/treatment provided to a patient; clinical indication; and clinical outcome.)

7c.) Complete item 7C only if you are making a claim of significant therapeutic distinction. Claims of significant therapeutic distinction when compared to the use of other, similar items that would otherwise share a code, must be described in detail. Articulate the clinical theory behind the claim, including differences in the product or its operation as it compares to currently coded products. Specify how the product results in a significantly improved medical outcome or significantly superior clinical outcome. (Please refer to the HCPCS decision tree for definitions and additional information.)
Provide the best available information related to your claim. Include copies of all articles that result from your systematic analysis of the available literature. Information submitted should be as complete as possible. Unfavorable articles should be provided.
with any appropriate rebuttal or explanation. If clinical articles submitted to substantiate a claim of significant therapeutic distinction cause you to exceed the overall 40-page limit, it is acceptable to exceed the 40-page limit only when the additional pages/documents contain clinical information provided to substantiate a claim of significant therapeutic distinction. When this occurs, the original application and all clinical documentation must be included in each of the 35 copies submitted to CMS.

8. Answer each of the questions A), B), and C) below:
   A) List any 3rd party payers that pay for this product
   B) List any codes that are currently being billed to those payers for this product.
   C) Explain why existing code categories are inadequate to describe the item.

9. A) Is this product prescribed by a health care professional?
   B) If yes - who prescribes the product and in what setting(s) is the product prescribed?

10. A) Is the item useful in the absence of an illness or injury?
    B) Explain:

FDA Information

11a.) Provide the date that the item/product was cleared for marketing by the FDA. If the product is exempt from FDA review and classification, please explain the basis for the exemption.

b.) Attach copy of the FDA approval letter including the 510(k) summary for those items that are approved using the 510(k) process. Also, if an item is cleared using the 510(k) process, identify the HCPCS codes, if applicable, that describe the predicate products listed in the 510(k) submission and explain why these codes do not adequately describe the item that is the subject of the HCPCS recommendation. In other words, if an item is listed as being substantially equivalent to another item(s) in an application for FDA marketing clearance, why is it not equivalent or comparable for coding purposes?

c.) For drugs and biologicals only: In order for an application for a code for a drug/biological can be considered timely and complete: FDA approval documentation may be submitted after the code application, but no later than March 31, 2016, provided all other application materials are complete and submitted by the deadline of January 4, 2016, AND provided the application for marketing approval has been submitted to the FDA by September 30, 2015. Applicants awaiting FDA clearance for drugs or biologicals at the January 4th submission deadline must submit with the application documentation evidencing submission for FDA approval, along with the date the application was submitted to the FDA.
Marketing and Cost

12a.) When was the item/product marketed in the United States?
Note For drugs and biologicals, the date of first sale are required.

12b.) For all items that are not drugs and not biologics, the applicant must submit 3 months of marketing experience following. This marketing experience must reflect sales in the US in the 3 months prior to submitting this coding recommendation. What is the total number of units sold in the U.S. and the total dollar amount in sales (Medicare, Medicaid and private insurance)? Estimations or projections are not acceptable. The information provided must represent actual volume of sales for the product for the period of time indicated. Note: For drugs and biologicals only, information regarding the number of units sold is not required.

13.) Identify the percent of use of the item across the following settings. For drugs/biologicals, provide the percentage of use for the setting in which this product is or would be administered.

Physician's Office: _______
Freestanding Ambulatory Care Clinics: _______
Patient's Home by patient: _______
Patient's Home by Health Care Provider: _______
Nursing Home/Skilled Nursing Facility: _______
Hospital Inpatient Facilities: _______
Hospital Outpatient Facility: _______
Other- (identify): _______
TOTAL VOLUME OF USE ACROSS ALL SETTINGS SHOULD EQUAL 100%

14a.) What is the Manufacturer’s Suggested Retail Price (MSRP) or list price of the item? This question must be answered for all items, except drugs/biologicals.

HCPCS Coding Recommendation submitted by:
Please provide complete contact information for the applicant as requested below.
Foreign applicants must provide a U.S. primary contact with U.S. contact information.
We use this information to contact applicants regarding upcoming meetings, questions regarding applications, and to make notifications of the status of applications. Applicants are CMS’ primary contacts for any information pertaining to HCPCS code applications.

Applicant’s Name:
Name of Corporation/Organization:
Mailing Address (street):
City, State, Zip
Direct dial Telephone Number and extension:
FAX Number:
E-Mail Address:
I attest that the information provided in this HCPCS coding recommendation is accurate and correct to the best of my knowledge.

__________________________________________ Date:________________________
Signature of Applicant

14b.) Is applicant the manufacturer? (check box below)

YES [ ]

*NO [ ]

14c.) *If the applicant is NOT the manufacturer, the manufacturer must provide the requested contact information and sign and date the attestation at item 14c (below).

Manufacturer Name (print):
Name of Corporation/Organization:
Mailing Address (street):
City, State, Zip
Telephone Number and extension:
FAX Number:
E-Mail Address:

I declare that the information in this application describing the product that is the subject of this application is true and accurate to the best of my knowledge.

__________________________________________ Date:________________________
Signature of Manufacturer

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1042. The time required to complete this information collection is estimated to average 11 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.